

**AMENDMENT**

**U.S. Appln. No. 09/485,320**

the certified copy of the priority document in the outstanding Office Action.

Hence, Applicants respectfully request that the Examiner confirm receipt of the certified copy of the priority document.

On page 2 of the Office Action, the Examiner rejects Claims 8-12 under 35 U.S.C. § 112, second paragraph.

Specifically, the Examiner states that Claim 8 is indefinite in the recitation of "unidentified clinical syndrome in middle-aged elderly women, inclusive of menopausal syndrome".

~~Applicants hereby cancel Claim 8 thereby rendering moot~~  
the Examiner's rejection.

Further, in view of the cancellation of Claim 8, Applicants hereby amend the dependencies of Claims 9 and 11 to make such dependent on Claim 1.

In addition, the Examiner states that Claim 10 (sic Claim 9) is confusing in the recitation of "is a food form". Further, the Examiner states that with respect to the expression "granules, capsules and tablets" in Claim 10, these items would appear to be pharmaceuticals, rather than foods.

Applicants respectfully submit that the Examiner's rejection has been met by amending Claim 9 to change "which is in a food form" to recite -- wherein said composition is a food composition --; and by the amendments to Claim 10.

As to the Examiner's objection to the expression "granules", powders (sic), capsules and tablets", Applicants respectfully submit that the Examiner's rejection is improper since a food can be in granular form, in powder form, as well as in capsules and tablets which are dissolvable in water.

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In addition, the Examiner rejects Claim 11 for containing a typographical omission of the word "in" prior to "a pharmaceutical".

Applicants hereby amend Claim 11 to correct this typographical error.

Accordingly, Applicants respectfully submit that the claims clearly and definitely recite the invention of interest, and thus request withdrawal of the Examiner's rejection.

In addition, on page 2 of the Office Action, the Examiner rejects Claim 3 under 35 U.S.C. § 112 first paragraph.

Specifically, the Examiner contends that the method recited in Claim 3 employs novel bacterial strains, and therefore requests a Statement of Availability be filed with respect to the deposited strains.

Accordingly, Applicants submit herewith an appropriate Statement of Availability thereby rendering moot the Examiner's rejection.

On page 3 of the Office Action, the Examiner rejects Claims 1-4, 6 and 8 under 35 U.S.C. § 102(a) (sic § 102(b)) as being anticipated by, or in the alternative, under 35 U.S.C. § 103 as being obvious over Chang et al in view of Balows et al.

Specifically, the Examiner states that Chang et al discloses a composition comprising soybean milk and a microbial strain of *Bacteroides* which appears to be identical to the presently claimed strain and composition, since the strain is found in feces and is capable of degrading a composition comprising isoflavone daidzein to equol. The Examiner contends

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that *Bacteroides* strains are found in feces as demonstrated by Balows et al.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Chang et al teaches metabolism of daidzein by intestinal bacteria found in human feces. Further, Balows et al teaches that normal feces contains *Bacteroides fragilis*.

However, neither Chang et al nor Balows et al teach or suggest using a *Streptococcus intermedius* or *Streptococcus constellatus* strain as recited in amended Claim 1 (Support for the amendments to Claim 1 can be found in cancelled Claim 2).

The composition of amended Claim 1 comprises at least one of the microbial strains *Streptococcus intermedius* and *Streptococcus constellatus*, and thereby can be used <sup>to</sup> prevent and alleviate unidentified clinical syndromes and conditions associated with menopause in middle-aged to elderly women. It is unobvious from the cited references what type of microorganism can be used to provide a composition with such an effect. ✓

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in Chang et al alone or when combined with the teachings of Balows et al, and thus request withdrawal of the Examiner's rejection.

On page 4 of the Office Action, the Examiner rejects Claims 1-10 under 35 U.S.C. § 102(a) as being anticipated by, or in the alternative, under 35 U.S.C. § 103 as being obvious of Ishikawa et al.

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Specifically, the Examiner states that Ishikawa et al discloses a composition comprising soybean milk and a microbial strain of *Streptococcus*.

In addition, on page 5 of the Office Action, the Examiner rejects Claims 1-12 under 35 U.S.C. § 103 as being unpatentable over Ishikawa et al in view of Halpin-Dohnalek et al.

The Examiner notes that Ishikawa et al does not teach a pharmaceutical dosage form. However, the Examiner states that Halpin-Dohnalek et al teaches that a composition comprising live ~~microorganisms can be provided in a capsule or tablet form.~~

Thus, the Examiner contends that it would have been obvious to modify the composition of Ishikawa et al by providing such in a tablet or capsule form as taught by Halpin-Dohnalek et al.

For the following reasons, Applicants respectfully traverse the Examiner's rejections.

Ishikawa et al was published on September 16, 1997, i.e., after Applicants' priority date of August 5, 1997. Hence, the Examiner's rejections have been rendered moot by the sworn translation into English of Applicants' priority document filed simultaneously herewith.

In any event, the Examiner is requested to note that the *Streptococcus* strains recited in Claim 3 are *Streptococcus intermedius* and *Streptococcus constellatus* strains, and not other strains of *Streptococcus*, for example, *Streptococcus thermophilus* disclosed in Ishikawa et al.

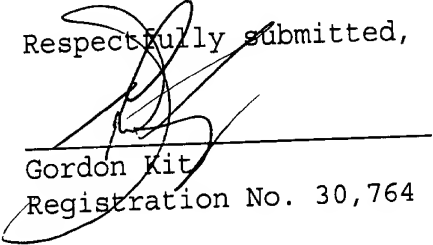
In view of the amendments to the claims and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

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The Examiner is invited to contact the undersigned at the below listed number on any questions which might arise.

Respectfully submitted,



Gordon Kit  
Registration No. 30,764

SUGHRUE MION, PLLC

2100 Pennsylvania Avenue, N.W.  
Washington, D.C. 20037-3213

Telephone: (202) 293-7860

Facsimile: (202) 293-7860

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## A P P E N D I X

### Marked-Up Version of Changes

#### IN THE CLAIMS:

Claims 2 and 8 are being cancelled

The claims are amended as follows:

Claim 1. (Amended) A composition comprising a daidzein-containing substance and at least one [a] strain of microorganism capable of metabolizing daidzein to equol as essential ingredients, whereas said strain is selected from the group consisting of Streptococcus intermedius and Streptococcus constellatus.

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Claim 3. (Amended) The composition according to Claim 1 wherein the strain of microorganism capable of metabolizing daidzein to equol is at least one member selected from the group consisting of [Bacteroides E-23-15, which has been deposited as FERM BP-6435,] Streptococcus E-23-17, which has been deposited as FERM BP-6436, and Streptococcus A6G-225, which has been deposited as FERM BP-6437.

Claim 9. (Amended) The composition according to Claim [8] 1, [which is in a food form] wherein said composition is a food composition.

Claim 10. (Amended) The composition according to Claim 9 wherein the food [form] is selected from the group consisting of a drink [drinks], dairy product [products], and fermented milk, or said composition is in the form selected from the group consisting of a bar [bars], [granules] granule, [powders] powder, capsule [capsules], and [tablets] tablet.

Claim 11. (Amended) The composition according to Claim [8] 1, which is in a pharmaceutical dosage form.